BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Sucrose Octanoate Esters
(PC Code 035300)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Sucrose Octanoate Esters
(PC Code 035300)

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I. Executive Summary

A. IDENTITY

The technical grade active ingredient (TGAI)/manufacturing-use product (MUP), "Avachem Sucrose Octanoate Manufacturing Use Product," consists of 85.43% sucrose octanoate esters [(" -D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate], made from a caprylic fatty acid ester derived from an edible oil or fat, and sucrose, a sugar which is a regular part of the diet of humans and animals. The end-use product (EP), "Avachem Sucrose Octanoate [40%]," contains 40% sucrose octanoate esters.

B. USE/USAGE

Avachem Sucrose Octanoate [40%] is a spray for use on a) various crops to control soft-bodied insects and mites, b) mushroom growing media to control sciarid flies, and c) adult honey bees to control *Varroa* mites. The use is classified as a food crop application.

C. RISK ASSESSMENT

No unreasonable adverse effects on humans or the environment are anticipated from aggregate exposure to Avachem Sucrose Octanoate Manufacturing Use Product or Avachem Sucrose Octanoate [40%]. This includes all anticipated exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoints

No toxicological endpoints are expected. Mammalian toxicology information from the open scientific literature and data were submitted to adequately satisfy data requirements to support the registration. Submitted information and data for the TGAI/MUP and the end-use product indicate Toxicity Category IV for acute oral, acute dermal, and acute inhalation toxicity; and for

primary dermal irritation. Neither the TGAI/MUP, nor the end-use product, is a dermal sensitizer. The data reported for primary eye irritation studies show that the test substance was moderately to severely irritating, and is thus a Toxicity Category I when the TGAI/MUP is used, and Toxicity Category II when the end-use product is tested.

b. Human Exposure

While exposure to the general population is expected to be low, worker exposure will occur. Appropriate protective wear and precautionary label language will mitigate vulnerability to the worker.

c. Risk Assessment

The Biopesticides and Pollution Prevention Division (BPPD) has not identified any subchronic, chronic, immune, endocrine, dietary or nondietary exposure issues with respect to sucrose octanoate esters as relates to children or the general U.S. population. Ocular risk to applicators is mitigated providing the label directions are followed. No toxicological endpoints are expected, and there is limited exposure of the general public to this product when used according to the label instructions. The Agency has considered sucrose octanoate esters in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product.

2. Ecological Risk Assessment

a. Ecological Toxicity Endpoints

Data waivers were requested and granted for ecological testing requirements because no toxic endpoints are expected, based on submitted mammalian data and information from the open scientific literature. An acute contact honey bee toxicity study demonstrated that sucrose octanoate esters are practically non-toxic to honey bees ($LD_{50} > 80$: g/bee).

b. Ecological Exposure

The active ingredient does not persist in the environment and biodegrades within approximately five days at approximately 20-27°C, in both aerobic and anaerobic conditions.

c. Risk Assessment

Risk to other organisms is expected to be minimal due to the low chances of exposure to the environment. The Agency posits sucrose octanoate esters, used according to label directions, will not result in significant adverse effects to wildlife or other organisms.

D. DATA GAPS / LABELING

There are no data gaps. Because of sucrose octanoate esters' Toxicity Category I for primary eye irritation, certain precautionary labeling is required to mitigate risks associated with proposed uses (see Labeling Rationale for details).

II. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name:	Sucrose octanoate esters
Chemical Name:	Sucrose octanoate esters [("-D-glucopyranosyl, $-D-fructofuranosyl-octanoate), mono, di-, and triesters of sucrose octanoate]
CAS Numbers:	42922-74-7 and 58064-47-4
Trade and Other Names:	Avachem Sucrose Octanoate Manufacturing Use Product, Avachem Sucrose Octanoate [40%]

OPP Chemical Code: 035300

Basic Manufacturer: Manufactured for:
AVA Chemical Ventures, L.L.C.
80 Rochester Avenue
Suite 214
Portsmouth, NH 03801

B. USE PROFILE

Proposed uses and application methods for sucrose octanoate esters include the following:

Type of Pesticide: Biochemical insecticide/miticide

Use Sites: Sucrose octanoate esters is for field, greenhouse and nursery use on any type of agricultural commodity (including certain non-food ornamentals); as well as on mushroom growing media and on adult honey bees.

Formulation Types: Liquid

Method and Rates of Application: Most conventional ground spray application equipment may be used. Shake or stir before use, adding the appropriate quantity to water, with agitation. Maintain gentle agitation during application. The proposed label specifies application rates a) between 0.8% and 1.0% volume/volume (v/v) for foliarly applied spray, b) between 1.25% and 2.50% v/v for mushroom growing media, and c) of 0.625% v/v for application to honey bees.

Use Practice Limitations: Do not allow workers into treated areas for 48 hours following application.

Timing: Application to foliage or adult honey bees should be initiated as soon as the target pest is observed. Mushroom growing media applications are to be made prior to spawning.

C. ESTIMATED USAGE

Although the Experimental Use Permit (EUP) issued in 2000 allowed the application 25 gallons of active ingredient over 50 acres in the state of California, no sucrose octanoate esters were actually applied under the experimental program (due to the unexpected unavailability of the test plot acreage). The EUP issued in 2002 allowed the application of 33 gallons of active ingredient over 100 acres in the state of California.

D. DATA REQUIREMENTS

BPPD reviewed data requirements for granting this registration under Section 3(c)(5) of FIFRA. Mammalian toxicology and ecological effects data requirements for sucrose octanoate esters were fulfilled. Product analysis data requirements are adequately satisfied.

E. REGULATORY HISTORY

On February 23, 1999, EPA received an application from AVA Chemical Ventures, L.L.C. for two new products with the new active ingredient, sucrose octanoate esters. A notice of receipt of the application for registration of sucrose octanoate (C_8 fatty acid mono-, di- and triesters of sucrose octanoate and sucrose dioctanoate) ("-D-glucopyranoside, $-D-fructofuranosyl, monooctanoate and dioctanoate) was published in the Federal Register on August 11, 1999 (64 FR 43701) with a 30-day comment period. No comments were received following this publication.

Note that the Agency and the registrant agreed to represent the active ingredient name as sucrose octanoate esters [("-D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] on the product labels and Confidential Statements of Formula and the

tolerance exemption expression. This name is synonymous with the name used in the Federal Register notice of receipt of August 11, 1999 (64 FR 43701).

On September 9, 1999, EPA published a Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals (sucrose fatty acid esters) in or on Food (8E4926, 64 FR 49010) with a 30-day comment period. No comments were received.

The EPA determined that the designation "sucrose fatty acid esters" is too broad, in that it could include other compounds not intended by the registrant, and for which the Agency has not reviewed relevant data. The data and information submitted by the registrant in support of the petition cover an exemption from the requirement of a tolerance for sucrose octanoate esters, which have been identified as the specific type of sucrose fatty acid esters that act as the active ingredient in the registrant's pending products. EPA's general policy is to establish a tolerance or exemption from the requirement of a tolerance for the actual active ingredient contained in the registrant's products. Because the active ingredient for which the registrant actually is petitioning is technically defined as sucrose octanoate esters [("-D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate], all discussions in this document (and the tolerance exemption expression established in the associated Final Rule for this new active ingredient) refer only to "sucrose octanoate esters [("-D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate]." Hereinafter EPA uses the term "sucrose octanoate esters" to mean sucrose octanoate esters [("-D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate].

On August 14, 2000, EPA received an application from the United States Department of Agriculture's Agricultural Research Service (USDA/ARS) for an Experimental Use Permit (EUP) covering the use of sucrose octanoate esters to evaluate control of the glassy-winged sharp shooter on non-bearing grape vines. On September 15, 2000, the Agency granted the EUP (65 FR 76259) to use 25 gallons/year of the biochemical active ingredient sucrose octanoate esters on 50 acres in the state of California.

On April 24, 2002, EPA received an application from AVA Chemical Ventures, L.L.C., on the behalf of the USDA/ARS, for a new Experimental Use Permit (EUP) covering the use of sucrose octanoate esters to evaluate control of the glassy-winged sharp shooter on non-bearing/post harvest citrus in addition to non-bearing grape vines. On May 31, 2002, the Agency granted the EUP (67 FR 43598) to use 33 gallons/year of the biochemical active ingredient sucrose octanoate esters on 100 acres in the state of California.

F. CLASSIFICATION

On January 14, 1997, the Biochemical Classification Committee determined that the insecticide/miticide sucrose octanoate esters are functionally identical and structurally similar to naturally occurring sucrose fatty acid esters, and so are eligible for testing using the biochemical reduced data requirements. Following review of the full data set submitted in support of the registration applications, which demonstrated a non-toxic, indirect mode of action for the active ingredient, the committee on July 2, 2002, amended the report by granting the "biochemical pesticide" designation to sucrose octanoate esters (Ref. 1).

G. FOOD CLEARANCES/TOLERANCES

On September 9, 1999, EPA published a Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food (8E4926, 64 FR 49010) with a 30-day comment period. No comments were received. A final rule establishing an exemption from the requirement of a tolerance is being published in association with this document. There are no Codex tolerances for sucrose octanoate esters.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for the technical grade/manufacturing-use product and the end-use product are met.

1. Product Identity and Mode of Action

a. Product Identity:

The technical grade active ingredient/manufacturing-use product, Avachem Sucrose Octanoate Manufacturing Use Product, consists of 85.43% sucrose octanoate esters [("-D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] and the end-use product, Avachem Sucrose Octanoate [40%], 40% sucrose octanoate esters.

b. Mode of Action:

The mode of action is physical and non-toxic; the surfactant effect of sucrose octanoate esters de-waxes the cuticle of the target insect, causing it to dessicate.

2. Physical And Chemical Properties Assessment

The physical and chemical characteristics of the TGAI/MUP and the end-use product were submitted to support the registration. They are summarized in Table 1.

Table 1. Product chemistry data requirements:

Product Chemistry (MRID 444880-01, as amended by 451974-01, 451974-02, 454103-01 and, 454103-02)	TGAI/MP	EP
151B-10 (880.1100): Product identity	Avachem Sucrose Octanoate Manufacturing Use Product, the technical product, consists of 85.43% sucrose octanoate esters and 14.57% other ingredients	Avachem Sucrose Octanoate [40%], the end-use product, contains 40% sucrose octanoate esters
151B-11 (880.1620): Formulation process	An acceptable description of the manufacturing process was submitted.	The product is formulated via a simple mixing process without any chemical reactions.
151B-12 (880.1400): Discussion of formulation of unintentional impurities	Acceptable nominal concentrations and certified limits were reported for the manufacturing impurities.	No impurities of toxicologic concern are formed during the formulation process.
151B-13 (880.1700): Preliminary analysis	Data obtained from the five-batch analysis demonstrate that the analytical method is precise and accurate.	No five-batch preliminary analysis data were submitted, but none are required since the end-use product is not manufactured via an integrated system, and because the TGAI/MUP will be registered simultaneously with the EP.
880.1750: Certified limits	The certified limits for the active ingredient and other impurities are acceptable.	Acceptable nominal concentrations and certified limits were reported for the other (inert) ingredient in the formulation.
880.1800: Enforcement analytical method	The analytical method is liquid chromatography (HPLC).	An acceptable liquid chromatography (HPLC) analytical method was submitted.

Product Chemistry (MRID 444880-01, as amended by 451974-01, 451974-02, 454103-01 and, 454103-02)	**TGAI/MP**	**EP**
Physical/Chemical Properties (MRID 444158-02, as amended by MRIDs 446101-02, 447634-01, and 451974-02)	**TGAI/MUP**	**EP**
880.6302: Color	Amber	Amber
880.6303: Physical State	Liquid	Liquid
880.6304: Odor	Faint sweet smell	Faint sweet smell
880.7200: Melting Point	NA, not a solid	Not required per 40 CFR § 158.190
880.7220: Boiling Point	Decomposes above 105°C	Not required per 40 CFR § 158.190
880.7300: Density, Bulk Density, or Specific Gravity	8.75 to 9.50 lbs/gal	8.50 to 9.00 lbs/gal
880.7840: Solubility	Forms an emulsion with water	Not required per 40 CFR § 158.190
880.7050: Vapor Pressure	<5 mm Hg	Not required per 40 CFR § 158.190
880.7370: Dissociation constant	NA	NA
880.7550: Octanol/water partition coefficient	Unknown	Not required per 40 CFR § 158.190
880.7000: pH	NA	7.0
880.6313: Stability	Stable below 40°C	Not required per 40 CFR §158.190

Product Chemistry (MRID 444880-01, as amended by 451974-01, 451974-02, 454103-01 and, 454103-02)	TGAI/MP	EP
880.6314: Oxidizing or Reduction Action	NA, does not contain an oxidizing or reducing agent	NA, does not contain an oxidizing or reducing agent
880.6315: Flammability/Flame Extension	None; decomposes above 105°C	NA, does not contain a combustible liquid
880.6316: Explodability	NA, is not potentially explosive	NA, is not potentially explosive
880.6317: Storage Stability	NA	At least 1year at 40°C based on shelf-life tests
880.7100: Viscosity	Not required per 40 CFR §158.190	500 to 2000 CP at 25°C
880.6319: Miscibility	NA, is not to be diluted with petroleum solvents	Totally miscible in water
880.6320: Corrosion Characteristics	NA	Non-corrosive to metals, plastics and glass
880.6321: Dielectric Breakdown Voltage	Not required per 40 CFR §158.190	NA, is not to be used around electrical equipment

B. HUMAN HEALTH ASSESSMENT

Information and data submitted to support the registration application of the technical grade/manufacturing-use product active ingredient, Avachem Sucrose Octanoate Manufacturing Use Product, and the end-use product, Avachem Sucrose Octanoate [40%], adequately satisfy the food and non-food use requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides.

Excepting ocular exposure, the overall toxicological risk from human exposure to sucrose octanoate esters is negligible.

1. Toxicology Assessment

Adequate mammalian toxicology information and data are available and support registration of the products containing the active ingredient sucrose octanoate esters. New studies were contracted by the registrant only for primary eye irritation and primary dermal irritation. Data waivers were requested and granted for all other toxicity data requirements. Publically available information/data were submitted, in lieu of studies, as part of the scientific justification necessary to support the data waiver requests (Refs. 2, 3, 6). In addition, the Agency has found additional relevant data from additional public sources, including the National Toxicology Program (NTP), which have been of value to the Agency's review of this application (Ref. 4). The submitted information/data, in combination, were found equivalent to what would normally be provided by guideline studies, and therefore would likely have been adequate to meet each toxicology requirement, had they been submitted as such pursuant to 40 CFR 152.90 (b)(4). More detailed analyses of these data and information can be found in specific Agency reviews of the studies and technical literature (Refs. 4, 5 and 7).

a. Acute Toxicity

The registrant submitted acceptable data and information from the open technical literature (Refs. 2 and 3) to justify the data waiver request and satisfy the requirement for acute toxicity studies. Based on the submitted information/data and additional relevant data found by the Agency from public sources, including the NTP (Ref. 4), BPPD has categorized both the manufacturing-use and end-use sucrose octanoate esters products as Toxicity Category IV for acute oral toxicity, acute dermal toxicity and acute inhalation toxicity. On the strength of a report showing no hypersensitivity responses or incidents among laboratory workers regularly exposed for up to six years to sucrose octanoate esters (aerosols or dried residues), BPPD has determined that neither product is a sensitizer, and has waived the hypersensitivity study (Ref. 5).

Following ocular instillation of 0.1 mL of undiluted manufacturing-use product into the eyes of rabbits, moderate to severe eye irritation and mild corneal opacity was observed in the treated eyes of all rabbits at 24 hours post-dosing and persisted in one rabbit to 21 days post-dosing. Mild iritis was exhibited in three rabbits at 24-hours post-dosing and persisted in one rabbit to 72 hours. This classifies Avachem Sucrose Octanoate Manufacturing Use Product as Toxicity Category I. Following ocular instillation of 0.1 mL of undiluted end-use product into the eyes of rabbits, moderate to severe eye irritation was observed in the treated eyes of all six rabbits at 72 hours post-dosing, was mild at seven days, and cleared by 14 days. Mild corneal opacity was observed in all six rabbits at 24 hours, and persisted to seven days in one rabbit, then cleared by 14 days post-dosing. Mild iritis persisted in four rabbits to 72 hours, then cleared. This classifies Avachem Sucrose Octanoate [40%] as Toxicity Category II.

Following dermal application of 0.5 mL of undiluted manufacturing-use product to the skin of rabbits, five rabbits exhibited very slight erythema and one exhibited well-defined erythema at one hour post-treatment. Very slight erythema persisted on four rabbits to 24 hours, then cleared. No edema was observed on any rabbit. Following dermal application of 0.5 mL of undiluted end-use product to the skin of rabbits, very slight erythema was exhibited by six rabbits at 0.5 hour post-treatment and five rabbits exhibited very slight to slight edema. All symptoms cleared by 24 hours. The results from these two studies place both the manufacturing-use and end-use sucrose octanoate esters products in Toxicity Category IV for primary dermal irritation. Based on the submitted information for hypersensitivity, sucrose octanoate esters is not a dermal sensitizer. Agency reviews are available in the docket (Ref. 5).

b. Genotoxicity and Mutagenicity

No guideline studies were submitted, but it was determined that none are required because the registrant submitted published information from the open, technical literature to scientifically justify waivers for these studies (Refs. 2 and 3). The submitted data/information demonstrate that sucrose octanoate esters are not genotoxic and/or mutagenic, nor is the active ingredient structurally and/or chemically similar to known mutagens or known classes of mutagens (Ref. 5).

A study reported by the NTP shows a sucrose octanoate esters constituent, octanoic acid, to be negative for genotoxicity/mutagenicity (Ref. 4).

c. Other Subdivision M Toxicity Data Requirements

Due to the low toxicity of sucrose octanoate esters (as demonstrated in the cited open technical literature (Refs. 2, 3, 5, 6 and 7)), the Agency granted waivers from all Subdivision M toxicity data requirements, including the immune response, 90-day feeding and teratogenicity studies. In addition, a sucrose octanoate esters constituent, octanoic acid, is considered a nonteratogenetic compound even at the very high dose rate of 18.75 mmoles/kg (Ref. 4).

Data Waivers (Refs. 2, 3 and 6) were requested for the following studies:

Acute oral toxicity (OPPTS 870.1100)
Acute dermal toxicity (OPPTS 870.1200)
Acute inhalation (OPPTS 870.1300)
Hypersensitivity study (OPPTS 870.2600)
Studies to detect genotoxicity (OPPTS 870.5300)
Immune response (OPPTS 880.3800)

Mammalian mutagenicity tests (OPPTS 870.5195)
90-Day Feeding (OPPTS 870.3100)
Teratogenicity (OPPTS 870.3700)

The registrant's rationale to support the waivers is that considerable sucrose octanoate esters safety data are available (Refs. 2, 3 and 6). The active ingredient, derived from edible vegetable oils, edible tallow or hydrogenated edible tallow, has been FDA-approved for use as emulsifiers in certain processed foods and as post-harvest protective coatings for certain fruits since 1983. In 1995, FDA expanded the range of foods in which sucrose octanoate esters are permitted, to include use in emulsifiers, stabilizers, and texturizers in chewing gum, confections, and frostings; texturizers in surimi-based fabricated seafood products; and emulsifiers in coffee and tea beverages with added dairy ingredients and/or dairy product analogs (60 FR 44755). Sucrose octanoate esters' constituent sugars and fatty acids are normal parts of the human diet, and the Agency knows of no instance where they have been associated with any toxic effects related to the consumption of food. Due to this knowledge of sucrose octanoate esters' presence in the human diet (Ref. 4), the summarized safety data (Ref. 2), the NTP data (Ref. 4), and the recent primary eye and primary dermal irritation testing, EPA believes sucrose octanoate esters are unlikely to be carcinogenic or have other long-term toxic effects. See also memos from R. S. Jones to D. Greenway, February 14, 2000 (Ref. 5) and D. Greenway to R. S. Jones, August 7, 2002 (Ref. 7).

Mammalian toxicity data for sucrose octanoate esters are summarized in Table 2.

Table 2. Toxicity data requirements

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
152-10, 870.1100	Acute oral toxicity in rats and mice	Data waiver granted (see text for details) Toxicity Category IV (MUP and EP)	444158-03 and Amendment No. 1
152-11, 870.1200	Acute dermal toxicity	Data waiver granted (see text for details) Toxicity Category IV (MUP and EP)	444158-03 and Amendment No. 1, and 444158-04
152-12, 870.1300	Acute inhalation toxicity	Data waiver granted (see text for details) Toxicity Category IV (MUP and EP)	None; not a likely pathway of exposure
152-13, 870.2400	Primary eye irritation in rabbits	Toxicity Category I (MUP) Toxicity Category II (EP)	446101-05 446101-06
152-14, 870.2500	Primary dermal irritation in rabbits	Toxicity Category IV (MUP) Toxicity Category IV (EP)	446101-03 446101-04

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
152-15, 870.2600	Dermal sensitization	Data waiver granted (see text for details) Not a sensitizer	444158-04
152-17, 870.5300	Studies to detect genotoxicity	Data waiver granted (see text for details)	NA
152-18, 870.8700	Cellular immune response	Data waiver granted (see text for details)	NA
152-19, 870.5195	Mammalian mutagenicity test	Data waiver granted (see text for details)	NA
152-20, 870.3100	90-Day Feeding	Data waiver granted (see text for details)	NA
152-23, 870.3700	Teratogenicity	Data waiver granted (see text for details)	NA

d. Effects on the Endocrine System

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program,

the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for sucrose octanoate esters.

2. Dose Response Assessment

No toxicological endpoints are expected.

3. Dietary Exposure and Risk Characterization

a. Dietary

i. Food

Because sucrose octaonate esters are the mono-, di- and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or edible vegetable oils, there is a great likelihood of exposure to sucrose octanoate esters' components for most, if not all individuals, including infants and children. Thus, sucrose octanoate esters may be considered a normal part of the human diet. Because the sucrose octanoate esters' constituent sucrose (table sugar, to which humans and animals are regularly exposed) is the primary photosynthetic product of all higher plants, and the constituent octanoic acid (caprylic acid) is a common fatty acid in plants, any residues of sucrose octanoate esters on treated plants would be indistinguishable from

background levels of the compounds (Ref. 4). Toxicological endpoints are not expected; therefore, risk from the consumption of residues is not expected for the general population, including infants and children. An acceptable daily intake (ADI) of sucrose octaonate esters for humans was estimated to be up to16 mg/kg body weight/day, which is equivalent to 2.82 lb (1.28 kg) of sucrose octaonate esters per day for a 176 lb person. In studies with rats ands humans, it was demonstrated that sucrose octaonate esters were rapidly hydrolyzed and absorbed by the body (Ref. 5). To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to sucrose octanoate esters. Even if there is a significant increase in exposure to sucrose octanoate esters due to its use as a pesticide, the acute toxicity information and data submitted by the registrant demonstrating extremely low mammalian toxicity (Toxicity Category IV) indicate that risk associated with acute exposures by the oral, dermal and inhalation routes would be low to non-existent.

ii. Drinking Water

No drinking water exposure is expected, as sucrose octanoate esters are not soluble in water, do not persist in the environment and biodegrade within approximately five days at approximately 20-27BC, in both aerobic and anaerobic conditions (Ref. 5). Because sucrose octanoate esters have extremely low toxicity, have been approved for food use by FDA, and are present as direct food additives in many foods, should exposure through drinking water occur, no risk is anticipated.

b. Other Non-occupational Exposure

The potential for non-dietary exposure to sucrose octanoate esters residues for the general population, including infants and children, is unlikely because potential use sites are commercial, agricultural, and large-scale horticultural. Sucrose octanoate esters constituent sugars and fatty acids are normal parts of the human diet. While there exists a great likelihood of prior exposure for most, if not all, individuals, any increased exposure due to the proposed products would be negligible.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Significant additional human exposure to sucrose octanoate esters is not expected in residential, school and day care areas since uses are limited to commercial, agricultural and large-scale horticultural settings.

a. Occupational Exposure

Agricultural use of sucrose octanoate esters is subject to the Worker Protection Standard (WPS), requiring Personal Protective Equipment (PPE), *i.e*., a long-sleeved shirt, long pants, shoes plus socks, and protective eyewear; and a 48 hour Restricted Entry Interval (REI).

b. Residential, School and Day Care Exposure and Risk Characterization

Because toxicological endpoints are not expected, risk from the consumption of residues is not expected for populations, including infants and children, in residential, school and day care settings.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure will be protective for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. In this instance, based on all the available information, the Agency concludes that sucrose octanoate esters are practically non-toxic to mammals, including infants and children. Thus, there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply. Sucrose octanoate esters'

components are found naturally in many foods already consumed by infants and children. And, as no toxic endpoints are expected, any hazard is impossible to determine (other than ocular). As a result, EPA has not used a margin of exposure approach to assess the safety of sucrose octanoate esters.

6. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure to sucrose octanoate esters by field workers and applicators may occur via oral and dermal routes. These risks are measured via the acute toxicity studies and information submitted to support registration. The oral toxicity information and data for sucrose octanoate esters showed no toxicity (Toxicity Category IV); the risks anticipated from oral exposure are considered minimal. Because the inhalation route is not a likely pathway of exposure, and based on sucrose octanoate esters safety data from the open, technical literature, the risks anticipated for this route of exposure are also considered minimal (Toxicity Category IV).

BPPD concluded that the submitted acute dermal toxicity information indicated no toxicity (Toxicity Category IV). Study results also demonstrated no significant dermal irritation (Toxicity Category IV). Furthermore, BPPD has concluded that sucrose octanoate esters are not skin sensitizers. Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low risk exposure scenarios and are negligible, when appropriate protective clothing is used.

Aggregate exposure to sucrose octanoate esters by the consumer would include other sources in addition to the limited amount on the agricultural products. Sucrose octanoate esters constituent sugars and fatty acids are normal parts of the human diet. While there exists a great likelihood of prior exposure for most, if not all, individuals, any increased exposure due to the proposed products would be negligible.

7. Cumulative Effects

Except through ocular exposure, sucrose octanoate esters are not toxic and it is not anticipated there would be cumulative effects from common mechanisms of toxicity. Risks to eyes can be prevented by the use of required protective eyewear (goggles or face shield).

8. Risk Characterization

The Agency has considered sucrose octanoate esters in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of Avachem Sucrose Octanoate [40%] when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The end use product Avachem Sucrose Octanoate [40%] is intended for agricultural and large-scale horticultural use. When applied according to the proposed label directions, no direct exposure of birds or aquatic organisms to Sucrose Octanoate [40%] is expected to occur. Acceptable information/data were submitted from the open technical literature to support the data requirements for avian acute oral toxicity, avian dietary toxicity, freshwater fish LC_{50}, freshwater invertebrate LC_{50}, and non-target plants. Based on the data, the Agency concludes that it is unlikely that any toxic effects will occur in birds, freshwater fish, freshwater aquatic invertebrates, and/or non-target plants when the product containing sucrose octanoate esters is used according to label directions (Ref. 5).

A request for a waiver from the non-target insect studies requirement was adequately supported by a) an acute contact honey bee toxicity study from which the Agency determined that the active ingredient may be classified as practically non-toxic to honey bees (LD_{50} is > 80 µg active ingredient/bee, Ref. 8), and b) three supplemental non-target insect studies obtained from the open technical literature which indicate that sucrose octanoate esters are relatively non-toxic to certain non-target, beneficial, insects (Ref. 5).

As a result of BPPD's assessment of the information and data described above, organism/ecological effects studies were waived for these particular uses of Avachem Sucrose Octanoate [40%]. However, standard precautionary label statements under "Environmental Hazards" are presented on the label.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because the Tier I studies were waived. Risk is minimal due to the lack of exposure, low toxicity, use pattern, and application methods.

3. Ecological Exposure and Risk Characterization

The active ingredient does not persist in the environment and biodegrades within approximately five days at approximately 20-27°C, in both aerobic and anaerobic conditions. Minimal potential for exposure exists to insects, fish and other non-target wildlife as a result of Avachem Sucrose Octanoate [40%] use.

D. EFFICACY DATA

No efficacy data are required, because no public health uses are involved. However, acceptable product performance data were submitted, and demonstrated activity against aphids, pear pyslla and whitefly.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, the fatty acid composition of sucrose octanoate esters accounts for its surfactant-type physical mode of action against the target pests, and is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, and will act as a pesticide to control soft-bodies insects, satisfying Criteria "C." Criteria "D" is satisfied by the data submitted and the products' low toxicity when used according to the label directions.

Therefore, sucrose octanoate esters are eligible for registration. The uses are listed in Table 4, Appendix A.

B. REGULATORY POSITION

1. Unconditional Registration

All data requirements have been fulfilled and/or waived by the Agency and the Biopesticides and Pollution Prevention Division recommends unconditional registration of products which contain sucrose octanoate esters as their sole active ingredient.

2. Tolerances for Food Uses and/or Exemptions

EPA received a pesticide petition (8E4926) from AVA Chemical Ventures, L.L.C., proposing [pursuant to section 408(b)(2)(D) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346], to amend 40 CFR Part 180 by establishing an exemption from the requirement of a tolerance for the biochemical pesticide, sucrose fatty acid esters, in or on all food commodities.

EPA determined the designation "sucrose fatty acid esters" to be too broad. The active ingredient for which the registrant actually petitioned is technically defined as sucrose octanoate esters [("-D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate]. Per section II. E. of this document, the tolerance exemption expression established in the associated Final Rule for this new active ingredient will be for "sucrose octanoate esters [("-D-glucopyranosyl-$-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate]."

3. CODEX Harmonization

There are no CODEX values for sucrose octanoate esters.

4. Nonfood Re/Registrations

There are no non-food issues at this time. The non-food uses are listed in Appendix A, Table 4.

5. Risk Mitigation

There exits a risk from ocular exposure. Risks to workers are mitigated by label language requiring protective clothing and a 48-hour re-entry interval.

6. Endangered Species Statement

Given the species-specific action of this biochemical pesticide, the intended use pattern, the results of toxicity and exposure data from the public scientific literature and data submitted by the applicant, the Agency has determined that this action will have no effect on currently listed endangered and threatened species.

C. LABELING RATIONALE

It is the Agency's position that the labeling of Avachem Sucrose Octanoate [40%] and the technical grade active ingredient/manufacturing-use product, Avachem Sucrose Octanoate

Manufacturing Use Product, containing, respectively, 40% and 85.43% sucrose octanoate esters, complies with current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard

This end-use product comes under the provisions of the Worker Protection Standards (WPS). PPE (long-sleeved shirt and long pants, shoes plus socks, and protective eyewear) and REI (48-hour) required.

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for Avachem Sucrose Octanoate Manufacturing Use Product and Avachem Sucrose Octanoate [40%] and concluded that the proposed precautionary labeling (*i.e.*, Signal Word, First Aid and other label statements) adequately mitigates any risks associated with the proposed uses.

Technical Product Precautionary Labeling: For Avachem Sucrose Octanoate Manufacturing Use Product – "DANGER"

Hazards to Humans and Domestic Animals:

DANGER: CORROSIVE. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by the poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

End-Use Product Precautionary Labeling: For Avachem Sucrose Octanoate [40%] – "WARNING."

Hazards to Humans and Domestic Animals:

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
-Call a poison control center or doctor for treatment advice.

If swallowed:

-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by the poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: Although sucrose octanoate esters are considered non-toxic to the environment, the environmental hazards statement is nevertheless required on the end-use product's label.

3. Application Rate

It is the Agency's position that the labeling for the pesticide product containing sucrose octanoate esters complies with current pesticide labeling requirements. The Agency has not stipulated a maximum number of applications for the active ingredient. The proposed label specifies application rates a) between 0.8% and 1.0% volume/volume (v/v) for foliarly applied spray, b) between 1.25% and 2.50% v/v for mushroom growing media, and c) of 0.625% v/v for application to honey bees. The diluent is water. For foliar uses, the finished spray solution may be applied at seven to ten day intervals, up to and including the day of harvest. Mushroom growing media (casing and/or compost) is to be treated prior to spawning. Applications to adult honey bees may be repeated three times per infestation (the limit stipulated by the applicant), at seven to ten day intervals.

D. LABELING

(1) Product name: **Avachem Sucrose Octanoate Manufacturing Use Product**

Active Ingredient:
Sucrose Octanoate Esters ("-D-Glucopyranosyl,$-D-fructofuranosyl-octanoate),
mono, di-, and triesters of sucrose octanoate..... . . . . .85.43%
Other Ingredients:. 14.57%

Total 100.00%

Signal word is "DANGER." Ocular exposure risk precautions are appropriate.

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (DANGER)

(2) Product name: **Avachem Sucrose Octanoate [40%]**

Active Ingredient:
Sucrose Octanoate Esters ("-D-Glucopyranosyl,$-D-fructofuranosyl-octanoate), mono, di-, and triesters of sucrose octanoate..... . . . . .40.0%
Other Ingredient:. 60.0%

Total 100.00%

Signal word is "WARNING." Ocular exposure risk precautions are appropriate.

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (WARNING)

V. Actions Required by Registrants

There are no data requirements, label changes or other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

VI. Appendix A

Table 4 lists the use sites for the end-use product. The labels for both products are also attached.

Table 4. End-Use Product Name, Use Sites, Registration/Reregistration

Avachem Sucrose Octanoate [40%] Use Sites: Field Crops (including certain non-food ornamentals), Mushroom Growing Media, Adult Honey Bees	Official date registered:

VII. References

1. USEPA; Amendment of the January 14, 1997, Classification Committee decision on sucrose fatty acid esters. R. S. Jones, July 2, 2002.

2. Barrington, T. and C. L. Hartman. Sucrose Fatty Acid Esters-Safety Data in Support of Petition Proposing a Temporary (sic) Exemption From the Requirement of a Tolerance for Use in All Food Commodities (MRID 444158-03), October 2, 1997.

3. Barrington, T. and W. L. Biehn. Sucrose Fatty Acid Esters-Safety Data in Support of Petition Proposing an Exemption From the Requirement of a Tolerance for Use in All Food Commodities, Amendment No. 1 to MRID 444158-03, July 13, 1998

4. USEPA; Brief Summary of Toxicity Information to Support Registration/Tolerance Exemptions for Sucrose Octanoate. R. S. Jones to D. Greenway; August 8, 2002.

5. USEPA; Science review in support of registration of sucrose octanoate esters. R. S. Jones to D. Greenway, February 14, 2000.

6. Barrington, A., Waiver Request; July 12, 2002.

7. USEPA; Sucrose Octanoate Esters; a Request for Concurrence on a Decision to Waive the Requirement for 90-Day Feeding (152-20) and Teratogenicity (152-23) Studies, Based on the Registrant's Correspondence of July 12, 2002. D. Greenway to R.S. Jones; August 7, 2002.

8. USEPA; Science review in support of registration of sucrose octanoate esters. R. S. Jones to D. Greenway, January 23, 2001.